



EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Manufacturer: FIAB SpA

Registered address: Via Costoli 4, 50039 Vicchio (FI), Italia

Single Registration Number: IT-MF-000005988

Basic UDI-DI: 803300326608000002SD

Product name/ Intended Purpose: Pre-wired ECG electrode

Models: See list in Attachment

Technical Documentation File: TDF 608

Risk Class (MDR Annex VIII): I

Conformity assessment procedure performed: Annex IV (EU Declaration of Conformity)

Technical standards and/or Common Specifications applied:

ANSI AAMI EC12 [2000 (R:2015)] - EN 1041
[2008/A1:2013] - EN 60601-1 [2006/A1:2013] - EN
60601-2-25 [2015] - EN ISO 10993-1 [2018] - EN ISO
13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1
[2016]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives, and are latex free

Signature:

Vicchio, 01/07/2021

Alberto Calabrò
Managing Director

Declaration Code EU-00000044-608

First issued: 07/06/2021

Last revised: 30/06/2021

Cod 99500038MD4B

Pagina 1 di 2





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Attachment of EU Declaration of Conformity – List of models

F9053 - F9053/10 - F9053N - F9053N/10 - F9053N/55 - F9053NRM - F9053NRM/80 - F9053P - F9053P/55 - F9053PR - F9053PR/10 - F9053PR/55 - F9053PRRM - F9053PRRM/80 - F9053RM - F9053RM/80 - F9054N - F9054N3/10 - F9054N3/55 - F9054NQ/RM/80 - F9054PR/55 - F9057N - F9057N/F2 - F9057NQ/60 - F9057NQ/RM/50 - F9057NRM - F9057P - F9057PQ/60 - F9057PR - F9057PRM - F9057PRRM - F9058/90NRM - F9058N - F9058N/60 - F9058N/F2 - F9058NRM - F9058P - F9058P/120 - F9058P/60 - F9058PR - F9058PRM - F9058PRRM - F9058PRRM/90

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Pagina 2 di 2

